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1 2 3 4 5 6 7 8 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Stephen C. Jensen (SBN 149894) steve.jensen@knobbe.com Stephen W. Larson (SBN 240844) stephen.larson@knobbe.com KNOBBE, MARTENS, OLSON & BEAR, L. 2040 Main Street Fourteenth Floor Irvine, CA 92614 Phone: (949) 760-0404 Facsimile: (949) 760-9502 Adam B. Powell (SBN 272725) adam.powell@knobbe.com KNOBBE, MARTENS, OLSON & BEAR, L. 3579 Valley Centre Drive San Diego, CA 92130 Phone: (858) 707-4000		
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10 11	Attorneys for Plaintiff		
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13	IN THE UNITED STATES DISTRICT COURT		
14	FOR THE CENTRAL DISTRICT OF CALIFORNIA		
15		_	
16 17	APPLIED MEDICAL RESOURCES CORPORATION, a California corporation,) Civil Action No. 8:23-cv-00268	
18	corporation,	COMPLAINT	
19	Plaintiff,	DEMAND FOR JURY TRIAL	
20	V.	}	
21	MEDTRONIC, INC., a Minnesota corporation,	}	
22	Defendant.	}	
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Plaintiff APPLIED MEDICAL RESOURCES CORPORATION ("Applied") hereby complains of Defendant MEDTRONIC, INC. ("Medtronic") and alleges as follows:

I. INTRODUCTION AND NATURE OF SUIT

- 1. Plaintiff Applied is a medical device company that is committed to providing affordable and accessible high-quality healthcare. Twenty years ago, the markets for endomechanical surgical devices—used to assist during laparoscopic surgeries in the abdomen—were substantially foreclosed. Applied fought to open several of these markets and the public greatly benefited following the opening of these once-foreclosed markets. Among other things, the public benefited from increased innovation, options, and value, including very positive economic and innovative impacts. The prices of critical medical devices, like trocars and retrieval bags, were significantly reduced and innovation flourished when previous anticompetitive practices were stopped.
- 2. Applied now brings claims to seek damages and permanently enjoin Medtronic's ongoing efforts to illegally block, foreclose or significantly limit and hinder competition in the relevant market for advanced bipolar energy devices, which are surgical devices that precisely control and deliver electrical current to cut tissue and seal vessels. Medtronic has conspired to "bundle" advanced bipolar energy devices in a way that is unhealthy for competition, hospitals, and patients in need of medical treatment.
- 3. Applied was founded in 1987 on the belief that innovation can deliver improved clinical outcomes while driving down the cost of healthcare. Applied has an unwavering commitment to team development, responsive and short supply lines, vertical integration, and exceptional innovations in products, practices, and procedures. This approach has enabled Applied to build a new generation medical device company with unique abilities to serve healthcare when economic demands are at a zenith. Applied uses innovation to couple

enhanced clinical outcomes with lower prices, and has enjoyed rapid growth and success in open markets by producing high-quality innovative products while increasing their availability through lower cost. Applied's highly automated, vertically integrated manufacturing environment makes Applied one of the most efficient medical device manufacturers in the world even though it manufactures its products in the United States. In 2015, Applied launched its Voyant Intelligent Energy System (Voyant), which is Applied's advanced bipolar device. The Voyant outperforms other advanced bipolar devices in numerous metrics and costs 15–20% less than competing devices.

- 4. Defendant Medtronic is the largest medical device company in the world, generating about \$30 billion per year in sales. Medtronic has a large, diverse, and expanding product portfolio covering numerous types of medical devices that it leverages to exclude competition—in addition to its massive M&A war chest, which Medtronic has previously used to effectively purchase its way out of competition. For example, Medtronic spent \$49.9 billion to acquire the surgical-supply company Covidien, and admitted that a main motivating factor for the deal was to enable Medtronic to bundle its products with Covidien's.
- 5. Medtronic is a monopolist and possesses monopoly power in the relevant market for advanced bipolar devices. The market is exceedingly concentrated, with Medtronic controlling a dominant 78% share with its "Ligasure" advanced bipolar device. Medtronic's market position is protected by high barriers to entry, including agreements with hospitals and group purchasing agreements ("GPOs"), medical regulations, large required investments, personnel costs, and more.
- 6. As explained in further detail below, Medtronic has engaged in anticompetitive conduct designed to maintain and enlarge its monopoly in the market for advanced bipolar devices. Such conduct includes exclusive dealing and anticompetitive bundling agreements with GPOs and hospitals that restrain

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trade in the market for advanced bipolar devices. GPOs were originally designed to reduce costs by allowing hospitals to aggregate their purchasing power, but GPO compensation has created conflicts of interest that result in dramatically higher prices. GPOs had agreed to "codes of conduct" after intense antitrust scrutiny in the early 2000s. More recently, however, Medtronic has entered anticompetitive agreements with GPOs that are inconsistent with those codes of conduct. Among other things, on information and belief, Medtronic agreed to pay GPOs exorbitant kickback fees in exchange for Medtronic being essentially the "sole source" of advanced bipolar devices.

7. Medtronic uses agreements with GPOs and hospitals in combination with its existing monopoly power to create and maintain monopoly power in new markets. Medtronic's agreements with GPOs and hospitals foreclose competition by, among other things, imposing anticompetitive bundling agreements that condition so-called "discounts" and "rebates," which customers feel compelled to meet due to the perceived enormous impact they could have on their overall financial bottom lines if they fail to meet the high market-share compliance requirements. Medtronic's "discounts" still result in high prices. However, Medtronic's prices after the "discounts" are not perceived by customers to be as high as they would be absent Medtronic's bundling agreements. Medtronic's contractual bundling requirements ensure that to earn these discounts and rebates, its customers must purchase not only advanced bipolar devices exclusively from Medtronic, but also many other types of medical devices in which Medtronic holds a dominant market share. The relative quantities and revenue of advanced bipolar devices ordered as part of these bundles is much smaller than the combined quantities and revenue of the other devices. Thus, the anticompetitive bundling prevents hospitals from purchasing advanced bipolar devices from an at least equally efficient competitor, like Applied, because the competitor cannot offer a low enough price to offset the entire total bundled exclusionary "discount."

- 8. Medtronic is selling its advanced bipolar devices below cost, after allocating the exclusionary discount given by Medtronic on the entire bundle to the advanced bipolar devices. This is supported by hospital statements that they will not purchase advanced bipolar devices from Applied—a more efficient competitor—at any price because of the exclusionary discounts that would be lost on other products.
- 9. Medtronic's contracts have such high market share requirements that they have the practical effect of preventing hospitals from evaluating competitive products during the term of the agreement, which causes many hospitals to renew without being able to make an informed choice. Medtronic also misleads hospitals to enter agreements by representing they will likely achieve sufficient sales to expect discounts, even though the discounts are (in reality) very difficult to realize in effective health care environments serving multiple clinical needs and specialties. Medtronic also directly targets customers that are considering competitive products, including Applied's Voyant devices. Medtronic's agreements with hospitals last for many years and will remain in place for the foreseeable, indefinite future. Medtronic's anticompetitive conduct has foreclosed competition for greater than 70% of sales in the advanced bipolar market.
- 10. Medtronic's conduct has no legitimate business purpose and does not provide any benefits to consumers. Instead, it is designed to increase profitability by foreclosing competition, driving up prices, and reducing research and development expenditure at the expense of improved clinical outcomes, product quality, and increased health care costs. Medtronic's conduct is designed to harm competition and providers. Medtronic's conduct has not lowered prices, increased efficiency, enhanced consumer appeal for advanced bipolar devices, or provided better products. To the contrary, the challenged conduct threatens the price, quality, and market-wide output of advanced bipolar products. Medtronic's

 conduct has resulted in supracompetitive prices, fewer choices, inferior products, and reduced innovation.

- 11. Medtronic is acutely aware that the only way to stop an innovative, competitive force from dismantling its monopolies is to engage in these predatory strategies. As a result of Medtronic's anticompetitive conduct, Applied has been substantially foreclosed from selling its groundbreaking advanced bipolar technology to hospitals. In open markets, Applied has a proven ability to drive down the cost of healthcare while increasing innovation and quality. As previously mentioned, trocars, retrieval bags and other laparoscopic instruments benefited from Applied's business model once those markets were freed from the bundled practices. In addition, international markets, where the bundle is not as prevalent, benefited from the Applied approach. Applied is uniquely positioned to drive down prices and increase product quality across the advanced bipolar market, but Medtronic's actions have prevented that from happening.
- 12. If Medtronic's conduct is permitted to continue, Applied and other competitors will be limited to a very small segment of the market. Enjoining Medtronic's anticompetitive behavior will open the market, allowing Applied and other competitors to compete fairly against Medtronic. As a result, the goals of the antitrust laws will be achieved by encouraging free and open competition. A successful lawsuit will lower prices, increase product quality, and increase market output. Accordingly, Applied brings this action.

II. PARTIES

- 13. Applied is a California corporation with its principal place of business at 22872 Avenida Empresa, Rancho Santa Margarita, California 92688, in Orange County, California.
- 14. Medtronic is a Minnesota corporation with its principal place of business at 710 Medtronic Parkway, Minneapolis, MN 55432. Medtronic

Orange County, California.

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III. JURISDICTION, VENUE AND INTERSTATE COMMERCE

maintains an office in Orange County, California, and a substantial workforce in

- 15. Applied brings multiple causes of action under federal antitrust law, including Section 1 and 2 of the Sherman Act, and Section 3 of the Clayton Act. Applied also brings related causes of action under California law. Those California causes of action are related to the federal claims such that they form part of the same case or controversy under Article III of the United States Constitution. Thus, this Court has subject-matter jurisdiction over all causes of action asserted herein under 15 U.S.C. §§ 15 and 26, and 28 U.S.C. §§ 1331, 1337 and 1367(a).
- 16. This Court has personal jurisdiction over Medtronic. Medtronic has substantial contacts with this District because it maintains an office in this District and employs a substantial workforce in this District, it regularly conducts substantial business in this District, and it has substantial ongoing ties to this District. Medtronic also committed the acts complained of herein throughout the country, including in this District. Medtronic can reasonably expect to be subject to the personal jurisdiction of this District.
- 17. Venue is proper in this District under 15 U.S.C. §§ 15 and 22, and under 28 U.S.C. § 1391(b) and (c). For venue purposes, Medtronic can be found in and transacts business in this District. In addition, Medtronic has engaged in the conduct alleged herein in this District. Medtronic's anticompetitive scheme has impacted and will impact rivals and hospitals in this District. Plaintiff Applied is one such rival, which maintains its business headquarters and employs a large workforce in this District.
- 18. Medtronic's misconduct occurs in and affects interstate commerce. Medtronic has contracted with GPOs and hospitals throughout the United States to foreclose its competitors. Both Ligasure and Voyant devices are manufactured

devices to all parts of the country, and it has used the below-pleaded anticompetitive conduct to restrain trade and monopolize commerce in the relevant market throughout the United States. Medtronic's anticompetitive conduct directly affects the price and volume of medical devices shipped in interstate commerce.

and shipped in interstate commerce. Medtronic regularly sells and ships Ligasure

IV. COMMON ALLEGATIONS

A. Relevant Products and Demand

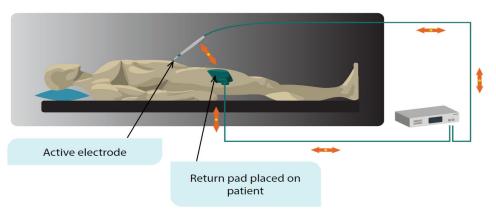
1. Electrosurgical Devices, Ultrasonic Devices, and Generators

- 19. Electrosurgical devices are surgical tools that deliver energy in the form of electrical current through a patient's tissue to generate a desired clinical effect. The devices are used to dissect tissue and vessels, coagulate (*i.e.*, stop bleeding) small vessels and seal vessels (*i.e.*, fuse the vessel walls to prevent blood flow) of various sizes. Electrosurgical devices are used in both open surgery and laparoscopic surgery. In laparoscopic surgery, surgical devices are passed through small holes in a patient's abdomen so that surgical procedures can be performed without making large incisions. Electrosurgical devices are commonly used in a broad range of laparoscopic and open surgical procedures because they make surgical intervention more effective and reduce patient trauma compared to mechanical cutting and sealing devices. Electrosurgical devices, particularly advanced bipolar devices discussed below, are among the most trusted and essential devices used by surgeons in the operating suite.
- 20. Procedures utilizing electrosurgical instruments require the use of a generator, a handpiece, active and return electrodes, cables connecting the generator to the other devices and a switch to activate during the procedure. Depending on the number of electrodes integrated within an electrosurgical handpiece, the design is either monopolar or bipolar. Handpieces may be reusable

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or disposable. Below is a description of the three primary types of electrosurgical devices and a fourth category of ultrasonic devices.

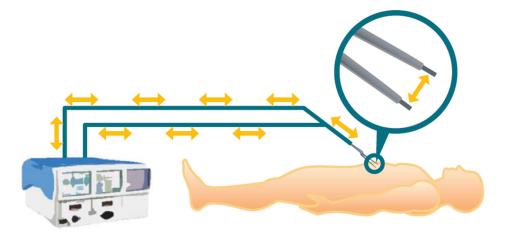
21. Monopolar devices have one active electrode for the energy to be released and use the patient's body as a ground. Monopolar instruments require a dispersive electrode, known as a grounding pad, which closes the electrical circuit safely through the patient's body and back to the generator, reducing tissue burns and ulceration. This is a diagram of a monopolar circuit:



Below is a picture of Medtronic's Force TriVerse monopolar device.



22. Standard bipolar devices have two integrated electrodes so that the current is passed from one electrode through the grasped tissue to the other electrode to complete the circuit. Bipolar devices increase patient safety because the energy does not travel through the patient's body, thereby not requiring a grounding pad. Rather, the two electrodes complete and contain the energy circuit. Delivering energy with a standard bipolar device to create a tissue effect is purely surgeon dependent – no advanced sealing algorithm or system indicators control the flow and termination of energy. Additionally, standard bipolar devices do not contain an integrated cutter to divide coagulated tissue bundles or vessels. This is a diagram of a standard bipolar circuit:



23. Below are examples of standard bipolar devices.



Bovie Bipolar Forceps

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24. Advanced bipolar devices perform multiple functions and eliminate the need for multiple devices or instrument exchanges, resulting in cost savings and efficiency improvements for the end user. Advanced bipolar devices use multiple electrodes and advanced energy control to achieve multiple functionality that allows a surgeon to dissect, seal and divide tissue. These devices have a primary vessel sealing function that closes off small or large vessels by electrically fusing the surrounding tissue to stop blood flow and safely divide a vessel with an integrated cutter. Advanced bipolar devices generally have a predetermined algorithm for sealing vessels and tissue that notifies the user (and cuts of the flow of energy) once the seal is complete with an "end tone," as opposed to relying on the surgeon to make that decision – one feature that distinguishes an advanced bipolar device from a standard bipolar device. These advanced sealing algorithms allow advanced bipolar devices to read electrical properties in the target tissue to provide an optimal amount of energy, removing any guesswork on the part of the surgeon. Advanced bipolar devices are typically provided as single-use disposables, which reduces the risk of cross-contamination. Advanced bipolar devices are provided in four major categories: standard length for laparoscopy, bariatric length for laparoscopy, open surgery vessel sealing for large vessels such as in gynecology and colorectal and open surgery vessel sealing when surgical space is confined such as ear, nose and throat surgery. Below are examples of Ligasure and Voyant advanced bipolar devices.

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1 2 3 4 5 6 7 8 Ligasure "Blunt Tip" Device 9 10 11 12 13

Voyant "5mm Fusion" Handpiece

25. Ultrasonic devices do not employ electrical current passing through patient tissue. Instead, these devices have blades, one of which oscillates at a very high frequency by converting electrical energy to mechanical energy (motion/friction). This allows these devices to cut/dissect through tissue by heat application. Ultrasonic devices can have quicker dissection capabilities than advanced bipolar devices but do not offer reliable vessel sealing capabilities. Ultrasonic devices are primarily used for dissecting as opposed to vessel sealing. As a result, ultrasonic devices are typically used for different surgical procedures and by different surgeons. Below are examples of Harmonic ultrasonic devices.

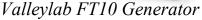


Ethicon Harmonic ACE+7 Shears

Close-Up Showing Blades

26. Generators are used to power electrosurgical and ultrasonic devices. Generally speaking, monopolar and standard bipolar generators are compatible with many brands of monopolar and standard bipolar cables and handpieces. However, generators for advanced bipolar and ultrasonic technologies generally work only with one brand of cable and handpiece. Below are examples of Medtronic and Applied generators.







Voyant Electrosurgical Generator

2. <u>Demand For Particular Product Features</u>

27. Surgeons performing both laparoscopic and open surgery in hospitals need to cut tissue and vessels, coagulate blood in tissue with very small vessels, and seal vessels of various sizes. General surgeons and specialists use these techniques in general, gynecological, colorectal, bariatric, urology, hepatobiliary, vascular and ear-nose-and-throat procedures. Surgeons typically choose a device that is well suited to the specific task, economical, efficient, and proficient. By choosing the correct device for the specific task, healthcare

providers can realize substantial savings through quicker and more accurate procedures with shorter recovery times. However, using a device that is not well suited to the specific task can cause longer surgical procedures and recovery times, and result in worse outcomes.

- 28. The following are some of the considerations that affect what kind or kinds of devices are suitable for use in a particular procedure:
 - a. The amount of time that a surgeon must spend cutting, coagulating, and sealing tissues or vessels for a particular procedure;
 - b. If the procedure involves relatively more dissecting, coagulating, or sealing of vessels;
 - c. If the surgeon would need to frequently switch between dissecting, coagulating, or sealing of vessels;
 - d. The size of vessels to be sealed;
 - e. The importance of quickly preventing bleeding for clear viewing or visualization after tissue or a vessel has been cut;
 - f. How much thermal spread may unintentionally damage surrounding tissue;
 - g. Whether it is important for the device to detect when a vessel has been successfully sealed;
 - h. Using a device that offers effective, reliable vessel sealing, combined with efficient delivery of energy, affecting both length of procedure and time the patient is under anesthesia;
 - i. Patient characteristics, including whether the patient is obese or has a condition that impedes normal coagulation;
 - j. Whether a particular device would cause temporary injury, prolong patient recovery, and/or entail permanent scarring; and

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- k. For laparoscopic surgery, the amount of smoke that is generated and needs to be evacuated from the abdominal cavity for clear visualization.
- 29. Advanced bipolar devices have many advantages over monopolar and standard bipolar devices, particularly for certain procedures. Advanced bipolar devices perform multiple functions and eliminate the need for multiple devices, resulting in cost savings for the end user and, in turn, the patient. Advanced bipolar devices permit a surgeon to dissect, cut, seal and divide tissue without having to switch instruments. Advanced bipolar devices have a vessel sealing function that closes off small or large vessels to prevent blood flow through the vessel and integrated cutter to divide said vessel. They are also capable of sealing much smaller vessels efficiently and effectively. Advanced bipolar devices are also typically disposable instead of reusable, which reduces the risk of cross-contamination. However, monopolar and standard bipolar devices are less expensive.
- 30. Ultrasonic devices can perform cutting, coagulation and limited vessel sealing, but use a different technology that has significant disadvantages, particularly for certain applications. These devices are not reasonably interchangeable with advanced bipolar devices. As discussed, ultrasonic devices have two blades, one of which oscillates at a very high frequency. Unlike advanced bipolar devices, which use sophisticated algorithms to notify the user that the tissue is sealed by reading electrical properties in tissue, ultrasonic devices typically require the surgeon to determine when they believe the vessel seal is complete by visually inspecting the target tissue. The difference in technology means that ultrasonic devices perform differently from advanced bipolar devices in a number of respects. Although it is perceived that ultrasonic devices can cut more quickly, they also tend to be less reliable for sealing, particularly where larger vessels are concerned. Ultrasonic devices also produce

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27 28 significantly more heat, which causes unintended thermal damage if the surgeon needs to cut for a sustained period of time or in an anatomical region adjacent to sensitive tissue or underlying structures.

31. As a result, hospitals and surgeons recognize advanced bipolar devices as unique devices that cannot be replaced by monopolar, standard bipolar, or ultrasonic devices. Advanced bipolar devices therefore lack any reasonable substitute. For this and other reasons discussed in greater detail below, advanced bipolar devices constitute a unique relevant antitrust market.

Group Purchasing Organizations 3.

- 32. Like many other medical devices, advanced bipolar devices are often purchased by hospitals through group purchasing organizations or GPOnegotiated contracts. GPOs were originally designed to reduce costs by allowing hospitals to aggregate their purchasing power. According to a U.S. Government Accountability Office report, 98% of hospitals are members of a GPO and GPOs control more than 70% of non-labor purchases that hospitals make. That report explains that "a relatively small number of GPOs dominate the market for products sold through GPO contracts." As one medical executive explained, "if you refuse to sell through a group purchasing organization, or through drug wholesalers, you will not exist."
- 33. Premier is one the largest GPOs. Premier claims that its members include more than 4,400 U.S. hospitals and more than 225,000 other provider organizations. Premier claims it controls more than \$69 billion in purchases per year.
- 34. Because GPOs control such a large portion of purchases, GPOs have acted as gatekeepers to cut off competition and deter innovation. In 2002, the New York Times ran a series of stories about the anticompetitive conduct of GPOs and the resulting negative impact on patient care and innovation. The New York Times reported GPOs foreclosing innovators of life-saving technology from

 getting their products into the hands of doctors. The story explained the problem: "buying groups are financed not by the hospitals that buy products but by the companies that sell them. In other words, the groups take money from the very companies they are supposed to evaluate objectively." "The more hospitals spend on medical supplies, the more dollars [GPOs] get from the suppliers." One hospital labelled the fees paid by vendors to GPOs as "payola."

- 35. After the *New York Times* articles published, Congress held hearings. Congress discussed three "major concerns." First, conflicts of interest raising the "specter of critical health care decisions being influenced by financial ties to suppliers." Second, contracting practices "reduc[ing] competition and innovation in health care and narrow[ing] the ability of physicians to choose the best treatment for their patients." Such practices included sole-source agreements, high commitment levels (contractual provisions that oblige a hospital to purchase a high percentage of its requirements for a good or service), and bundling (contractual provisions that oblige a hospital to purchase most or all of its requirements for many unrelated products from a single seller). Third, GPOs ultimately do not get the best deal and "produce the worst of both worlds, little savings and fewer choices."
- 36. With pressure mounting to repeal their exception to anti-kickback laws, GPOs agreed to reform their practices and endorsed codes of conduct designed to prevent Congress from acting. For example, Premier promised to contract with more companies, stop investing in supply companies, and limit how much money it accepts from companies that contract with Premier. Premier promised to cap fees paid by suppliers at 3% and promised to no longer enter into sole-source agreements. Premier promised to reduce high commitment levels, to award only multisource agreements for surgeon-preference items (which would include advanced energy devices) and to stop bundling various products into a single contract. After the other two largest GPOs agreed to similar codes of

conduct, Congress seemed to believe the GPOs had effectively self-regulated to resolve its major concerns.

- 37. More recently, Premier has started quietly walking back its prior commitments. Premier's current "code of conduct" removed the prohibitions put in place earlier. Premier now permits sole-source agreements if they are reviewed by a Premier vice president and compliance departments. As discussed in more detail below, Applied is informed and believes that Premier and its performance groups recently began entering agreements with dominant suppliers that are effectively sole source and began charging fees higher than 3%, returning to the practices that were the catalyst for Congress's investigation twenty years ago.
- This development raises serious public concerns. A reoccurring 38. danger, which came to fruition before, occurs when a dominant supplier offers lucrative kickbacks to the major GPOs in exchange for their grant of sole-source agreements and acceptance of other contract terms that are not in the best interests of the hospitals. GPOs are highly incentivized to enter into such agreements because they will obtain higher kickback fees without (in their opinion) running afoul of the anti-kickback statute's "safe harbor" regulations for GPOs. Such practices allow dominant suppliers, like Medtronic, to pay high contractual administrative fees to "buy" a sole-source agreement that promises exclusive market share to Medtronic, thereby permitting the supplier to exclude competitors and charge inflated prices for medical equipment, while the GPO obtains higher revenues. The conflict is apparent because both the supplier and Premier are incentivized to agree to higher prices, as lower prices merely decrease revenue and profits for both. The supplier obviously benefits from increased prices, but Premier also benefits from increased fee revenues from both the higher prices and the higher fee percentages. The hospital members and consumers, however, suffer from higher prices, less competition, and fewer choices. The temptation

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for illicit agreements with dominant suppliers like Medtronic was, apparently, too high. The agreements are discussed in more detail below.

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Relevant Markets В.

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Relevant Product Market 1.

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There is no other product that serves as a reasonably interchangeable substitute for advanced bipolar devices. Surgeons that use them and hospitals that purchase them cannot turn to other products to efficiently accomplish the same procedural

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outcomes.

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Monopolar devices and standard bipolar devices are not adequate 40.

The relevant product market is the advanced bipolar device market.

substitutes for advanced bipolar devices. As discussed above, monopolar and standard bipolar devices serve a different surgical purpose from advanced bipolar devices. Advanced bipolar devices have a number of advantages compared to monopolar devices and standard bipolar devices, including the ability to dissect, cut, seal, and divide tissue without having to switch instruments, and all while having the benefit of advanced sealing algorithms dictating optimized surgical outcomes. Disposable advanced bipolar devices also reduce the potential for cross-contamination.

41. Ultrasonic devices, which Medtronic sells under its Sonicision line, are also not adequate substitutes for advanced bipolar devices. Medtronic is the second largest manufacturer of ultrasonic devices. As discussed, ultrasonic devices ('dissecting' devices) generally have different uses and disadvantages compared to advanced bipolar devices ('vessel sealing' devices). For example, ultrasonic devices are prone to over-heating during extended use. The overheating can be problematic for procedures that require cutting for a sustained period of time or in sensitive anatomical regions. Ultrasonic devices also tend to be less reliable for sealing larger vessels. As a result, ultrasonic devices are not well-suited to the same types of procedures as advanced bipolar devices. Thus,

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surgeons generally do not consider monopolar, standard bipolar, or ultrasonic devices as reasonable substitutes for advanced bipolar devices.

Industry participants recognize that other devices 42. interchangeable with advanced bipolar devices. Medtronic brands, sells and markets its Ligasure advanced bipolar and Sonicision ultrasonic product lines distinctly from each other. Johnson & Johnson ("J&J") does the same. J&J is the largest manufacturer of ultrasonic devices under the "Harmonic" brand offered by its Ethicon company. J&J had a "long-term vision of making harmonic technology critical in every type of surgery" and hoped that it would become the "standard of care" for many segments. J&J quickly realized, however, that the ultrasonic market, monopolar market, standard bipolar market, and advanced bipolar market differ from one another in important ways. For example, in 2008, J&J acquired SurgRx, the manufacturer of the "Enseal" branded advanced bipolar devices. Following the acquisition, J&J did not consolidate the two products or seek to migrate customers from one product to the other. Instead, J&J continues to market "Harmonic" and "Enseal" devices to address distinct demand by hospitals for ultrasonic and advanced bipolar devices.



ENSEAL X1 Curved Jaw Tissue Sealer

Similarly, in 2017, J&J acquired Megadyne Medical Products, 43. which was a supplier of monopolar and standard bipolar devices. following the acquisition, J&J did not attempt to consolidate its products or migrate customers from one product to another. Rather, J&J continues to market 1
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its Megadyne monopolar and standard bipolar devices along with its Harmonic ultrasonic devices and Enseal advanced bipolar devices to address demand for distinct product types by hospitals for all four types of devices.

- 44. Advanced bipolar devices have no reasonably interchangeable substitutes, and there is no significant cross-elasticity of demand between these devices and other products. Because of many factors, including price, performance, value and safety, there are no other significant economical substitutes for advanced bipolar devices. Even if other devices could provide acceptable performance at similar prices, few buyers would switch from advanced bipolar devices to such devices because doing so is time consuming and costly. Alternatives may also not fit safety guidelines and may also threaten the value proposition of the devices to hospitals by inadequate performance.
- 45. If a hypothetical monopolist were to become the only seller of advanced bipolar devices in the United States, and if at the time these products were sold at competitive prices, the hypothetical monopolist could profitably charge a small but significant non-transitory increase in price (a "SSNIP") for these products. That is, the hypothetical monopolist could profitably impose a permanent price hike an increase in its prices that was significant, non-transitory, and not justified by increased input costs. This circumstance by itself confirms that advanced bipolar devices constitute a distinct category of products for purposes of antitrust review.
- 46. The advanced bipolar device market is also explicitly recognized as such by device makers, hospitals, surgeons, industry experts, and disinterested observers. Advanced bipolar devices have peculiar characteristics and uses in comparison to other energy devices discussed above. Advanced bipolar devices also have distinct prices, distinct demand curves (independent sensitivity to price changes), and distinct marketing approaches compared to the other energy devices discussed above. Manufacturers, distributors, surgeons, and hospitals

regard each type of energy device as separately marketed, sold, and distributed

for uses that no other product can fulfill, and customers negotiate separate

contracts to purchase devices from each of the specific energy categories. Thus,

advanced bipolar devices constitute a relevant market or, in the alternative, a separate relevant submarket.

2. Relevant Geographic Market

47. The effective area of competition (or relevant geographic market) for the product market at issue in the present case is the United States. Hospitals in the U.S. must purchase their advanced bipolar devices from suppliers that serve the U.S. Those suppliers must meet certain regulations because advanced bipolar devices sold within the U.S. must satisfy FDA rules and regulations. Thus, customers in the U.S. cannot substitute advanced bipolar devices available outside the U.S. because those products would need U.S. regulatory approval. Advanced bipolar device manufacturers that sell in the U.S. also face assertions of patents and other intellectual property rights that are limited to the U.S. Advanced bipolar device manufacturers who make their products available in the U.S. sell to all parts of the country. There are no substantial geographic barriers within the U.S. due to transportation costs or regulation that prevent firms from selling advanced bipolar devices throughout the U.S.

C. <u>Medtronic Dominates The Advanced Bipolar Market</u>

48. Medtronic dominates the market for advanced bipolar devices. Medtronic has an about 78% market share and its position is protected by high barriers to entry and expansion. These market realities are described in more detail below.

1. <u>Medtronic Has Monopoly Power In The Advanced Bipolar</u> <u>Device Market</u>

49. The advanced bipolar device market is highly concentrated and comprised of a small number of market participants. Medtronic is the dominant

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seller of advanced bipolar devices in the United States. Medtronic has monopoly power in this market. Medtronic's Ligasure product makes up about 78% of overall sales in the advanced bipolar market and its market position is protected by strong barriers to expansion and entry. Medtronic can and does charge well in excess of a competitive price for its products.

Below is a chart of approximate market shares and total market value 50. for the advanced bipolar device market according to one independent third-party report.

	Advanced Bipolar Devices
Medtronic / Covidien	78.5%
Ethicon	11.5%
Olympus	6.3%
Others	3.7%
Market Value (\$M)	\$ 667.3

- 51. The Herfindahl-Hirschman Index ("HHI") is a measure to evaluate market concentration. A market's HHI is calculated by summing the squares of each market participant's market share. A market with an HHI above 2,500 is considered highly concentrated, a market with an HHI of 1,500 – 2,500 is considered moderately concentrated, and a market with an HHI below 1,500 is considered unconcentrated. Based on the reported market shares above, the HHI exceeds 6,300, which indicates the market is extremely concentrated.
- 52. The data from the third-party report discussed above includes Olympus in the advanced bipolar devices category. However, as discussed below, Olympus' product (Thunderbeat) is a combination device that is not a reasonable alternative to advanced bipolar devices. The Thunderbeat is a niche product that is not a reasonable substitute for advanced bipolar products as it features a core ultrasonic device design with some advanced bipolar capabilities.

Even including Olympus in the relevant market, however, Medtronic's share is over 78%. Excluding Olympus, Medtronic's share of advanced bipolar devices is over 83%. Excluding Olympus, the HHI increases to more than 7,100, which indicates the market is extremely concentrated.

- 53. As discussed throughout, ultrasonic devices are not reasonable alternatives to advanced bipolar devices. However, even if one were to combine the advanced bipolar and ultrasonic markets set forth in the third-party report discussed above, Medtronic's share would still exceed 50%. Using these market shares, the HHI would still exceed 4,200, which would still indicate the market is extremely concentrated.
- 54. Medtronic's market position is also protected by high barriers to entry and expansion ("market barriers"). Perhaps the most significant market barriers are Medtronic's trade restraints, exclusionary practices, entrenched monopoly, and history of anticompetitive conduct. Such conduct is described in more detail below.
- 55. Another market barrier is the requirement to form long-term agreements with GPOs, which provide a "gateway" to customers and control more than 70% of non-labor hospital purchases in the United States. Agreements with GPOs last many years and are often renewed.
- 56. An additional market barrier is the frequent requirement to form long-term sales relationships with hospitals. These relationships can take two to five years to cultivate before resulting in an actual supply contract. Since supplier needs are often met through long-term requirements and related contracts, the ability for new entrants to penetrate the market is extremely difficult because it requires securing rare, elusive supply contracts. These relationships are cultivated through the customer's experience with the supplier's service team and the use of the technology. The nature of Medtronic's restrictive contracting practices blocks a new, more effective competitor from building these

relationships and gaining comfort with the competitor's new technology. Medtronic, the incumbent, maintains an advantage secured by the contract restraints, exclusionary practices, and entrenched monopoly. Medtronic has numerous such relationships and contracts, including contracts with GPOs and long-term supply contracts at hospitals nationwide. Such contracts include long-term contracts.

- 57. Rules and regulations are another market barrier. Sellers must obtain regulatory approval from government offices, including the FDA, to market, distribute, and sell medical devices in the U.S.
- 58. Another market barrier is that manufacturers are required to make large capital investments, including in facilities and machinery. Such investments are required to achieve economies of scale. Firms need to produce enough products to be able to profitably sell them at market prices.
- 59. Another market barrier is that participation in the industry also requires a substantial portfolio of technology, intellectual property and know how. Sellers may need to license intellectual property rights from others and may need to develop their own portfolio.
- 60. An additional market barrier is the need to employ highly skilled professionals, including engineers, designers, doctors, and other individuals with technical backgrounds. Any seller in this market requires rarified technical proficiency.
- 61. An additional market barrier is switching costs arising from network effects, and the large investments required for electrical generators, which supply power to advanced bipolar devices. Medtronic has a large installed base of such generators at hospitals nationwide, which are not compatible with competitive advanced bipolar devices, like Voyant devices. Thus, Medtronic has already recouped the cost of providing the generators for many customers. While competitors need to factor in the cost of generators for new deals, Medtronic can

- rely on its existing generators that it provided to hospitals—often years ago. Hospitals are also financially locked into purchasing Medtronic products to support their installed Medtronic generators, which prevents hospitals from considering competitors and limits hospitals' practical consideration of switching to new market entrants. The practice of providing generators on loan significantly increases risks and switching cost for new entrants.
- 62. Additional market barriers include substantial research and development costs, logistical barriers, and commercial supply arrangements, which dissuade manufacturers of monopolar, standard bipolar, and ultrasonic devices from producing advanced bipolar devices. For example, manufacturers of other devices have recovered their research and development costs on those devices and are reluctant to incur the significant costs required to develop advanced bipolar devices, generators, and necessary accessories.
- 63. Another market barrier is brand recognition. Market participants must develop an established brand that becomes trusted by surgeons, hospitals, and GPOs. As discussed above, these relationships can be extremely difficult to develop with the customer secluded behind the barriers of Medtronic's contract restraints, exclusionary practices, and entrenched monopoly. For example, the founder of the New York Bariatric Group is a paid speaker, trainer and proctor for Medtronic. This group has excluded Voyant everywhere they operate and, if a hospital will not switch to Ligasure, refused to perform surgery at the hospital.
- 64. Medtronic has also limited competition through admittedly deceptive comparative marketing practices. In 2018, for example, once Medtronic had identified Voyant as a threat to Ligasure, Medtronic issued a lengthy, misleading brochure that sought to paint Voyant in a negative light compared to Ligasure and hinder the implementation of Voyant efforts at large facilities. To perform its "testing," Medtronic had to modify the Voyant handpiece to work with Medtronic's generator, thereby removing the intelligence

embedded in the Voyant device key and preventing the Voyant handpiece from running the optimized Voyant algorithm embedded in the key (plug) that connects only to a Voyant generator. Instead, Medtronic apparently ran the Ligasure algorithm (embedded in the Medtronic generator) on the Voyant system handpiece and used those jerry-rigged test results—certain of which could lead to damaging conclusions about Voyant—to conclude Voyant was lacking when compared to Ligasure. Medtronic then promoted its sham brochure on those "studies." In 2021, Medtronic submitted this brochure in connection with a tender offer—only to later sign a statement acknowledging that the brochure contained misleading methodologies and flaws. Nevertheless, to this day, Medtronic's brochure remains available on its website.

- 65. Thus, Medtronic's dominant market share and high market barriers indicate that Medtronic wields monopoly power in this market. Medtronic faces no threat that any existing or potential competitor can readily deprive it of sales by expansion or entry if it imposes a SSNIP, or if it imposes other onerous commercial terms that its customers would not accept in competitive markets.
- 66. Medtronic also can and does charge supracompetitive prices. For example, Applied offers its Voyant products at 15–20% less than Medtronic's pricing for its Ligasure products. In the absence of Medtronic's anticompetitive conduct, Medtronic would not be able to sustain its current inflated pricing model. In addition, Medtronic has also been increasing its average sales prices over time. As its customers renew their contracts, Medtronic systematically steers them to more expensive devices. For example, Medtronic has been replacing certain Ligasure devices with more expensive versions of such devices. The average sales price of Ligasure's "Blunt Tip" is approximately \$461, whereas Ligasure's "Maryland" average sales price is \$536. The Ligasure Maryland device was released years after the Ligasure Blunt Tip and offers very few, if any, clinical benefits over the Blunt Tip.

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2. Others Do Not Presently Assert Substantial Competitive Discipline On Medtronic

67. Others participate in the advanced bipolar market, but none presently asserts substantial competitive discipline on Medtronic. After Medtronic, Ethicon is the next largest seller in the advanced bipolar market. Ethicon's market share is approximately 12% and has fallen in the past decade. Ethicon's "Enseal" products have little prospect of future success and are a weaker offering compared to Ligasure. For example, unlike Ligasure and Voyant, which have separate seal and cut functions, the Enseal product line has historically integrated a single button/handle to do both at once, which means vessel sealing cannot occur without cutting simultaneously. This makes seal verification prior to cutting difficult and does not allow surgeons to confirm seal integrity prior to vessel transection. This technical limitation makes the legacy Enseal product unpopular Ethicon has recently redesigned this and unintuitive with many surgeons. limitation out of the Enseal product but with limited success. Ethicon also issued a nationwide recall for one of its newly redesigned Enseal advanced bipolar devices in 2019 based on reports of complications associated with intraoperative bleeding. One third-party market data report predicted that recall would "limit Ethicon's share within the advanced bipolar energy device market to some extent."

68. The third largest seller according to the industry data discussed above is Olympus, which sells a combination device under the brand name "Thunderbeat." To the extent Thunderbeat is part of the relevant market, it is not an efficient check on Medtronic. Thunderbeat is far more complex than either an advanced bipolar product or an ultrasonic product. This complexity causes a steep learning curve, which prevents many surgeons and hospitals from considering Thunderbeat. It also adds substantial production costs, which makes it difficult for Olympus to compete on price. Integration of both ultrasonic

technology as well as some advanced bipolar features has yielded outcomes that result in poor execution of both modalities. For example, the Thunderbeat jaws produce significant heat, more so than most other standalone ultrasonic devices, which can lead to unintended stray thermal damage. Thus, Thunderbeat is a niche product that is not a reasonable substitute for the advanced bipolar products discussed above.

3. Applied Could Provide A Competitive Check on Medtronic In The Absence Of Medtronic's Anticompetitive Conduct

- 69. While Applied makes a better product at a lower cost, and Applied has repeatedly received extremely positive feedback from hospitals about its technology, Applied has had limited success in selling its Voyant products because of Medtronic's anticompetitive efforts. As one third-party report explained, there has been "very limited adoption of other companies' products, such as Applied Medical's Voyant, even though such products may have a lower price point."
- 70. Absent Medtronic's anticompetitive conduct, Applied would provide a competitive check on Medtronic. Applied's founding belief is that innovation is the solution to cost. Thus, unlike other companies who use innovation to justify higher prices, Applied uses innovation to not only improve products, but to also lower prices through investment in process development and automation. Applied is a leader in many medical devices and is known for its many enabling technologies and its ability to implement genuine cost savings. Applied has maintained a consistent commitment to innovation by dedicating an unprecedented 20% of revenue to research and development in product and process innovation. This continued commitment to a process driven and integrated manufacturing environment has resulted in over 2,000,000 square feet of highly automated and efficient production facilities located primarily in California.

- 71. When many businesses were outsourcing, Applied kept its manufacturing in the United States, optimized its processes, increased vertical integration, and pursued a short and secure supply line. During the recent global supply chain collapse, this vertical integration and exceptional manufacturing model was put to the test. Applied continues to be a reliable source of products. Today, Applied has one of the most automated and efficient manufacturing environments of any medical device supplier in the world. Applied's manufacturing capabilities include: advanced metal processing, electrical discharge machining, high-speed milling, stamping, wire forming, mold manufacturing, injection molding, thermoset molding, liquid injection molding, metal injection molding, in-house sterilization, and much more. Applied's production plants are some of the largest and most technologically advanced in the world.
- 72. As a result, Applied is one of the most efficient medical device manufacturers in the world and is at least an equally efficient competitor to Medtronic, even though Applied manufactures its products in the United States. Indeed, owing to its revolutionary manufacturing process, Applied is more efficient than Medtronic at producing advanced bipolar devices. As a result, Applied can sell advanced bipolar devices at lower prices than Medtronic can without selling below cost.
- 73. Voyant also outperforms Ligasure in numerous metrics, including seal times, burst pressures and thermal spread. Seal time is the time it takes for a device to achieve a quality seal after activation. Burst pressure represents the pressure required to burst open a fully sealed vessel. Surgeons value this performance outcome above all others as this determines what level of confidence and reliability the device offers in being able to maintain a full fused artery or vein during and after surgery. Seals that are compromised and burst open would lead to additional therapy at the seal site during surgery to limit blood loss or

result in patient readmission if bleeding were to occur after a procedure is completed. Voyant devices typically have a 30-60% shorter seal time and 30-70% higher burst pressure compared to Ligasure devices of the same category. For example, one category of Voyant devices seals arteries in about 45% less time and has about a 60% higher average burst pressure compared to the Ligasure device of the same category. Thermal spread measurements provide the amount of lateral thermal damage generated to surrounding tissue after delivering energy to a vessel or tissue bundle. The Voyant sealing algorithm's efficiency aids in producing minimal thermal spread to surrounding tissue when in use. For example, the Voyant 5mm Fusion devices produce an average lateral thermal spread of 1.1mm while the comparable Ligasure Blunt Tip produces an average lateral thermal spread of 1.3mm. Voyant devices also use integrated intelligence to gather data during actual usage, which Applied engineers use to refine and evolve its sealing algorithm so customers obtain enhanced algorithms and performance with new handpieces. Absent Medtronic's anticompetitive conduct discussed below, Applied could serve as a competitive restraint on Medtronic.

D. Medtronic Dominates Other Markets

- 74. Medtronic is the largest medical device company in the world. Medtronic also operates in other markets in which Applied does not compete. Medtronic has a large, diverse, and expanding product portfolio covering numerous types of medical devices that it leverages to exclude competition. Depending on the hospital, Medtronic bundles many different types of products.
- 75. For example, Medtronic often bundles monopolar devices and stapling devices with advanced bipolar devices to exclude competition for advanced bipolar devices. Industry analysts, suppliers, GPOs, and hospitals all recognize that monopolar devices and stapling each constitute a distinct class of products that is sold in its own nationwide market.

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76. Below is a chart showing the approximate market shares of monopolar devices and stapling devices.

	Monopolar Devices	Stapling
Medtronic	73%	48.9%
Ethicon	17.8%	46.1%
Others	9.1%	5%
Market Value (\$M)	\$394.2	\$1,146.7

77. As shown above, the market value of the monopolar devices market is approximately \$394 million. The market is highly concentrated, with an HHI exceeding 5,500. Medtronic's market share of the monopolar devices market is approximately 73%. This market also has high market barriers similar to those discussed above, including FDA approval, large up-front investments, economies of scale, intellectual property barriers, the need to retain highly skilled professionals, brand recognition, and long-term relationships with hospitals and GPOs. Applied does not participate in the monopolar device market.

78. As shown above, the market value of the stapling market is more than \$1.1 billion. The market is highly concentrated, with an HHI exceeding 4,500. Medtronic's market share of the stapling market is about 50%. This market also has high market barriers similar to those discussed above, including FDA approval, large up-front investments, economies of scale, intellectual property barriers, the need to retain highly skilled professionals, brand recognition, and long-term relationships with hospitals and GPOs. Applied does not participate in the stapling market.

79. The combined market value of the monopolar device market and stapling market is more than \$1.5 billion. On information and belief, Medtronic's combined share of that total is at least \$825 million, which is larger than the

approximately \$650 million total market value of the advanced bipolar device market.

E. The Challenged Anticompetitive Conduct

80. Medtronic engaged in a variety of acts that, separately and together, prevent rivals from competing in the market for advanced bipolar devices. Medtronic's conduct has foreclosed competition for greater than 70% of all sales of advanced bipolar devices. Medtronic's conduct is described in more detail below.

1. Medtronic's Exclusionary Agreements With GPOs

- 81. Medtronic has entered into anticompetitive agreements with GPOs, including Premier, that are effectively "sole-source" agreements, which restrain trade in the market for advanced bipolar devices. On information and belief, Medtronic's GPO agreements typically have an initial term of three years and can be extended for additional years. As a practical matter, however, the terms of the agreements are much longer. Because Medtronic's GPO agreements practically last multiple three-year terms, the actual terms of the agreements are six years or more.
- 82. On information and belief, Medtronic and Premier agreed that Medtronic would pay Premier a kickback fee exceeding the standard 3% of sales in exchange for Premier making Medtronic effectively the "sole source" for any Premier members who purchase advanced bipolar devices. Premier has offered similar agreements to other companies.
- 83. In November of 2019, Premier visited Applied for a site visit. Premier wanted to discuss changes to its code of conduct, including eliminating the 3% cap on fees. Applied explained the pitfalls of going down that path, including the anticompetitive concerns addressed by the *New York Times* and Congress in the early 2000s.

- 84. In 2020, Applied bid on a Premier contract for advanced bipolar devices. Because Applied's average sales prices for Voyant are 25–30% lower than Medtronic's prices for Ligasure, on information and belief, Applied offered significantly better pricing compared to Medtronic. In July of 2021, Premier told Applied that it did not receive a national contract and that Premier awarded the contracts to each of "the" dominant suppliers (Medtronic for advanced bipolar and Ethicon for ultrasonic). Applied repeatedly asked Premier to confirm it did not accept a fee higher than 3% from Medtronic. Premier refused to provide such a confirmation. More recently, Premier's performance groups have sought to have Applied pay fees in excess of 3%, which Applied refused. On information and belief, Premier offered the contract to Medtronic despite significantly higher prices because Medtronic agreed to pay Premier more than 3% in fees.
- 85. As a result, the selection process by which Premier chose Medtronic was not competitive on the prices and merits of relevant products. Instead, Premier delivered substantial market share to Medtronic in exchange for high kickback fees. Such conduct restrains, rather than advances, competition on the merits, and results in a self-perpetuating cycle: the more Premier-member hospitals spend on Medtronic's products, the more money Premier receives from Medtronic, and thus the more influence Medtronic will have over Premier.
- 86. Premier's agreements have the effect of coercing Premier members to purchase advanced bipolar devices from Medtronic, thereby avoiding products made by other "non-approved" rival manufacturers. Even if hospitals could technically buy products from "non-approved" rivals, most hospitals do not do so for many reasons described below.
- 87. As a practical matter, it is very difficult, financially challenging and time consuming for hospitals to purchase products from "non-approved" sellers outside of the GPO contracts. Hospitals often believe it is not worth the time and effort to do so, because hospitals can face financial penalties imposed by the GPO

for doing so. As a result, competitors must demonstrate an overwhelmingly large benefit to break through the GPO contract to approach hospitals directly.

- 88. GPOs like Premier also have staff embedded in many hospitals' supply chain groups, which promote products covered by the GPO contract and attempt to dictate a hospital's purchasing directions.
- 89. Premier agreements include exclusionary bundled "tier" discounts across multiple product lines for purchasing set percentages of various products. These "tier" discounts are similar to the bundled hospital agreements discussed below and present similar anticompetitive issues.
- 90. Larger "member-owner" hospitals have an ownership interest in GPOs, including Premier, and collect portions of the kickback fees paid to the GPO based on smaller "affiliate" hospitals that purchase through the contract. Large "member-owner" hospitals can negotiate "secondary" agreements whereby Medtronic offers a larger bundle (discussed below) through the GPO. Such bundled contracts enhance Medtronic's exclusivity, further blocking competitors from making inroads with the "member-owner" hospitals. These anticompetitive actions ensure the "member-owner" hospitals stay "on contract" to encourage smaller "affiliate" hospitals to similarly stay "on contract."
- 91. Medtronic has entered similar agreements with large GPOs other than Premier. As a result, the majority of GPO members (including Premier members) who purchase advanced bipolar products do so from Medtronic through the GPO contract. Based on Premier's size and the large portion of hospital purchases that flow through GPOs, the Medtronic-Premier contract prevents a substantial number of hospitals in the U.S. from purchasing advanced bipolar devices from competitors other than Medtronic.
- 92. Medtronic is currently applying pressure to GPOs to get them to renew these agreements to further foreclose competition in the relevant market. If other GPOs succumb to such anticompetitive practices when their contracts are

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renewed, as Medtronic is pressuring them to do, it will create a cascade effect and quickly and inexorably tip the market in Medtronic's favor even more than it has already. Thus, Medtronic's conduct also constitutes an incipient violation that will cascade and substantially harm competition even more if it is not stopped.

2. Medtronic's Exclusionary Agreements With Hospitals

- 93. Medtronic has also entered anticompetitive agreements with individual hospitals and hospital systems. Medtronic has obliged customers to accept agreements that require the hospital to purchase most or all of their advanced bipolar devices from Medtronic. Medtronic does so through requirements contracts and bundled exclusionary discounts, which are discussed in detail below. Under these exclusive dealing agreements, Medtronic essentially becomes the exclusive provider for many years.
- 94. Medtronic's requirements agreements expressly require a hospital to purchase a set percentage of its advanced bipolar devices from Medtronic. Such agreements typically require the hospital to purchase between 80-100% of its advanced bipolar devices from Medtronic. Medtronic then audits compliance to ensure hospitals do not purchase from competitors, like Applied.
- 95. Medtronic also uses bundled exclusionary discount arrangements in its agreements, whereby Medtronic conditions discounts and rebates on the purchase of a variety of devices, including advanced bipolar devices. These bundles include both advanced bipolar devices, as well as monopolar devices, stapling, and other products.¹ Medtronic offers large bundles in which advanced bipolar devices, monopolar devices, stapling, and other products are sold at a "discount" when purchased as part of a customer's overall high market-share

¹ Although Applied identifies such exemplary products, Applied reserves the right to challenge Medtronic's bundling of additional products as the full scope and content of Medtronic's bundling is revealed through discovery.

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27 28 compliance. The quantities and revenue of advanced bipolar devices ordered as part of these bundles is much smaller than the quantities and revenue of the other devices because the needs of hospitals for these other devices, in terms of quantity, is much greater than the need for advanced bipolar devices.

- The total exclusionary discount on Medtronic's devices is very 96. significant because of the high volume and total cost of such devices. However, hospitals obtain that discount on the other products only if they also agree to purchase advanced bipolar devices from Medtronic. Such hospitals thus decline to purchase advanced bipolar devices from competitors, like Applied, because the competitor cannot offer a low enough price to offset the entire total bundled exclusionary discount. Competitors cannot profitably offer advanced bipolar devices when competing with the bundle because the exclusionary discount on the bundle far exceeds any reduction in price that could be available from an equally efficient competitor.
- Medtronic is selling its advanced bipolar devices below cost, after allocating the exclusionary discount given by Medtronic on the entire bundle to the advanced bipolar devices. This is supported by hospital statements that they will not purchase advanced bipolar devices from Applied—a more efficient competitor—at any price because of the exclusionary discounts that would be lost on other products. Because Applied is more efficient than Medtronic and nonetheless cannot sell its devices for a profit, Medtronic must be effectively selling its advanced bipolar devices below its average variable costs when allocating the exclusionary discount given by Medtronic on the entire bundle to the advanced bipolar devices. Indeed, hospitals have informed Applied that whatever price Applied offered would not make up for the bundled exclusionary discount.
- 98. Medtronic's bundling excludes equally and more efficient competitors from the advanced bipolar device market. Medtronic's bundling

forecloses competition both with respect to cost and the choice of, and access to, better surgical devices. This is to the detriment of health insurers, and ultimately consumers, in the form of higher prices paid for lower quality surgical devices, which contributes to high insurance costs that result in some patients being uninsured and unable to afford life-saving procedures. Medtronic's bundles create a powerful disincentive for hospitals to buy advanced bipolar devices from rivals, including Applied, for reasons that have nothing to do with the relative merits of the competing products. In most cases, hospitals are not economically capable of terminating Medtronic's bundled agreements as a practical matter.

- 99. Medtronic's exclusionary discount bundles have foreclosed competition in the advanced bipolar devices market. Medtronic's competitors, such as Applied, that operate in the advanced bipolar devices market, but not in the other markets, effectively cannot sell to hospitals that purchase advanced bipolar devices and the other bundled products. To match the total "discount" of Medtronic's exclusionary bundle, Applied and other smaller competitors would need to sell their advanced bipolar devices at a loss. Even though Medtronic's smaller competitors, including Applied, are willing to accept a lower margin, the smaller competitors cannot absorb the differential of the bundle.
- 100. The bundled exclusionary discount thus effectively forces Medtronic's smaller competitors out of the market. An equally efficient, less diversified seller, such as Applied, is no match for Medtronic's bundled discounts. Medtronic's bundles create a powerful or prohibitive disincentive for hospitals to buy advanced bipolar devices from rivals, including Applied, for reasons that have nothing to do with the relative merits of the competing products. This conduct, in conjunction with Medtronic's other anticompetitive conduct, has allowed Medtronic to maintain improperly its monopoly in the advanced bipolar devices market. Medtronic's conduct forecloses competition, denies hospitals the choice of, and access to, better and less expensive surgical devices, and harms

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 consumers in the form of ultimately higher prices and lower quality surgical devices.

- 101. Medtronic's conduct is widespread and has harmed competition in thousands of U.S. hospitals. On information and belief, many of Medtronic's agreements are of at least a three-year duration. Those agreements are often extended and, in practice, last far longer than three years. On information and belief, Medtronic uses a variety of contract terms to pressure customers to renew and remain under contract. For example, as discussed below, Medtronic includes terms in its contracts that effectively prevent a fair evaluation of competing products, which causes hospitals to sign extensions or new contracts without considering rival products.
- Applied and other equally efficient competitors' ability and opportunities to compete with Medtronic for advanced bipolar devices. Medtronic unlawfully leverages its monopoly power in other markets to coerce customers to accept its bundle and thereby purchase its advanced bipolar devices, and to gain and/or maintain its dominance in the advanced bipolar market. Medtronic's hospital agreements harm competition, boost Medtronic's sales of advanced bipolar devices, and thereby maintain and reinforce its domination and control of the advanced bipolar device market.

3. Medtronic's Overall Scheme of Anticompetitive Conduct

103. The anticompetitive aspects of each individual type of conduct are magnified and increased by the other categories of anticompetitive conduct. For example, Medtronic's agreement with GPOs, including Premier, prevent competitors from making inroads with many hospitals that tend to purchase directly through the GPO. Medtronic reinforces the effect of its GPO agreements by entering restrictive multi-year exclusive dealing agreements with hospitals in the form of requirements contracts and/or exclusionary bundled discounts.

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104. In addition to the anticompetitive effects discussed above, Medtronic reinforces its dominance in other ways. For example, the hospital agreements have the practical effect of preventing hospitals from evaluating competitive products during the term of the agreement. As compliance requirements approach 100%, hospitals often use what little leeway there is to purchase a small number of other products for specialty procedures or surgeon preference. This leaves insufficient leeway for hospitals to obtain the significant amount of competing products necessary to conduct a trial. Thus, customers often renew their contracts with Medtronic without even considering rival products, buttressing Medtronic's exclusive dealing and foreclosing competition for far longer than the initial term of the exclusive contract.

105. Medtronic also uses illusory promises when negotiating its agreements to coerce customers into entering agreements they otherwise would not have entered. For example, Medtronic may represent that a hospital will likely achieve sufficient sales and can expect sizable bundled discounts. In reality, however, such discounts may not be realized. Thus, Medtronic uses the asserted discount to undercut competitor prices but then charges the higher price These anticompetitive illusory promises allow Medtronic to anyway. simultaneously lessen competition and enjoy its full measure of monopoly pricing, to the even greater detriment of hospitals and consumers than when pricing is consistent with the representations made. Many hospitals are unable or unwilling to freely discuss the terms of their Medtronic agreements due to confidentiality provisions, which prevents Medtronic's rivals from exposing Medtronic's illusory promises. This harms competition in the market, boosts Medtronic's sales, and forces even more customers into Medtronic's exclusive contracts, further foreclosing the market to competition.

106. Medtronic also targets its conduct towards particular competitors when it knows those competitors are making progress with particular hospitals.

For example, Medtronic uses its illusory promises discussed above when it knows Applied is making inroads with a particular customer. As discussed above, Medtronic has also offered additional bundled exclusionary discounts when it knows Applied is making inroads with a particular customer. Medtronic has even offered additional discounts on the condition that the customer immediately stop evaluating Voyant.

107. Thus, Medtronic has engaged in a variety of categories of individual conduct that, individually and collectively, mutually enforce each other and work together to harm and foreclose competition in the market for advanced bipolar devices. Medtronic's conduct, individually and collectively, impairs competition in an unnecessarily restrictive way. In addition to its anticompetitive conduct, Medtronic actively deters customers from considering or purchasing from rival sellers, so that none of the rival sellers can gain a foothold and pose a genuine competitive threat. Medtronic is continuing to engage in this scheme of conduct, which continues to harm Applied and consumers by foreclosing competition in the advanced bipolar devices market. The conduct forms an overall scheme designed specifically to maintain Medtronic's monopoly power in the advanced bipolar devices market or in the alternative creates a dangerous probability that Medtronic will acquire such monopoly power.

4. Medtronic's Lack of Business Justifications

108. Medtronic lacks any legitimate business justification for any of its above-identified anticompetitive practices, each of which is illicit, and all of which Medtronic has cumulatively used to restrain trade and monopolize trade in the above-pleaded advanced bipolar device market. Even if Medtronic had a legitimate business purpose for any of its above practices, it could readily accomplish any such purpose by using less restrictive practices.

F. Medtronic Is Harming Competition and Consumers

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109. Medtronic's conduct threatens the price, quality, and market-wide output of advanced bipolar products. Medtronic's conduct has prevented or diminished rivals' competitiveness by preventing them from obtaining economies of scale that would further reduce prices, imposing barriers to entry for rivals, and reducing rivals' ability to constrain Medtronic's behavior. Medtronic's anticompetitive acquisition and maintenance of monopoly power and its restraints of trade have directly resulted in demonstrable harm to competitive processes in the affected markets, including an adverse effect on prices, fewer choices, inferior products, and limiting rivals' market penetration.

1. Medtronic's Supracompetitive Prices

anticompetitive 110. Medtronic's conduct resulted has in supracompetitive prices. Applied's Voyant products fulfill the same functions, offer the same features, and provide better performance than Medtronic's However, Applied offers them at prices that are Ligasure products. approximately 15–20% lower than Medtronic's prices for its Ligasure products. In the absence of Medtronic's anticompetitive conduct, Medtronic would not be able to sustain its pricing. Medtronic would have lost too much business by selling inferior products at such high prices and would have had to drop its prices. As discussed, Medtronic has also been increasing its average sales prices over time.

111. This stands in stark contrast to other medical device markets in which Applied was able to break in and create a competitive marketplace. In such other medical device markets, prices have been continually falling because of improving technology, economies of scale, and improved production methods. For example, J&J employed bundling in the trocar market until, in the face of regulatory and legal pressures, it modified its contracts to provide a carve-out that allowed hospitals to purchase products from smaller companies. As a result,

Applied was able to compete in the trocar market and sales prices decreased while quality and innovation increased. According to industry data, average sales prices for disposable trocars have decreased more than 25% since 2008. Opening up the market for advanced bipolar devices will similarly allow competition to flourish, increasing product quality and driving down costs.

2. Fewer Choices And Inferior Products

- 112. Medtronic's conduct has also resulted in fewer choices and inferior products. The vast majority of the market for advanced bipolar devices is dominated by Medtronic. In practice, Medtronic's anticompetitive behavior prevents most hospitals from having any choice at all for advanced bipolar devices. As discussed below, many hospitals have told Applied that they cannot purchase from Applied due to Medtronic's bundling.
- 113. Medtronic's anticompetitive conduct has also lowered the incentive for other market participants to innovate and dedicate resources to developing better advanced bipolar devices. For example, Ethicon offers a competing advanced bipolar product that has had limited success because of technical deficiencies. Ethicon has not dedicated the necessary resources to develop a product line that can meaningfully compete with Ligasure.
- 114. As a result, customers have suffered from a lack of choice, inferior product designs, and stagnating innovation. But for Medtronic's anticompetitive acts foreclosing substantial portions of the market, Applied, Ethicon, and others would have more incentive to dedicate more resources to capturing a larger percentage of this \$650+ million market. The result of such vigorous competition would be improved product quality, increased innovation, and lower prices.

3. Medtronic's Conduct Has No Pro-Competitive Benefit

115. Medtronic's conduct has no pro-competitive benefit. Medtronic's conduct has no legitimate business purpose and has no effect on improving Medtronic's efficiency or effectiveness at manufacturing advanced bipolar

devices. Medtronic's conduct also does not provide any additional benefits to consumers. Medtronic's conduct has not increased efficiency, enhanced consumer appeal for advanced bipolar devices, or provided better products for hospitals and hospital systems or consumers.

116. Medtronic's conduct has also not resulted in lower prices. Medtronic inflates its prices beyond competitive levels and then offers "discounts" that do not even bring its products back to competitive levels. Thus, Medtronic's "discounted" prices are higher than competitive levels and do not represent any discount at all compared to true competitive market prices. There is nothing to indicate that Medtronic's "discounts" have resulted in any actual cost savings to consumers.

4. Substantial Foreclosure

117. As discussed above, Medtronic has engaged in a variety of categories of individual conduct that, individually and collectively, mutually enforce each other and work together to substantially foreclose competition in the market for advanced bipolar devices. Medtronic's conduct thus forecloses competition and prevents customers from having the choice of, and access to, better surgical devices. By engaging in such anticompetitive conduct, Medtronic forecloses competitors from reaching hospital purchasers.

118. As discussed above, Medtronic has an about 78% market share in the relevant market and has entered long-term agreements with GPOs and large numbers of hospitals that have foreclosed competition. Applied has encountered Medtronic's practices at numerous hospitals nationwide and has been unsuccessful in competing even in hospitals that Applied believed would be most likely to convert to Applied. For example, Applied was unable to make sales to hospitals who are existing customers who had been purchasing trocars from Applied for years.

- 119. This foreclosure of competition in the United States is in stark contrast to Europe, where Applied has made significant Voyant sales because bundling is subject to strict regulatory scrutiny. In the United States, Applied has a roughly 3% share of the market for advanced bipolar devices; in Europe, Applied's market share is climbing, with Applied's market share approaching 40 and 50% in several European countries. Applied's experience supports that Medtronic is widely engaging in the above practices and has substantially foreclosed competition nationwide. Applied estimates Medtronic's conduct has foreclosed, or substantially hindered, competition in over 70% of the U.S. market for advanced bipolar devices.
- 120. Applied has encountered Medtronic's anticompetitive conduct at numerous hospitals nationwide. The following are some examples of the many customers who told Applied that they could not purchase Voyant because of Medtronic contracts: New York University, Mt. Sinai, Westchester New York, Lehigh Valley, Sentara, Tift, Memorial Hermann, Ochsner Health, Community Memorial Health System, Captis Healthcare Organization, Emory, UPMC, Cleveland Clinic, Robert Wood Johnson, Main Line Health, Tampa General, Parkview, Northwestern, Mercy St. Louis, Banner, University of Utah, and University of California health systems (including UCLA).
- 121. Below are some of the reasons hospitals have provided for not purchasing Voyant.
 - a. Despite a savings exceeding \$1 million from switching to Voyant, the hospital could not purchase from Applied because of its contractual obligations to Medtronic. Moving a product in any category away from Medtronic would result in the hospital falling out of compliance and losing its entire Medtronic rebate exceeding 20% for all products.

- b. The hospital indicated it would purchase Voyant based on positive clinical feedback and a \$1.6 million savings. The hospital then reversed its decision because of Medtronic's large bundle.
- c. The hospital recognized that Applied set the gold standard for responsiveness, high quality products, and availability. But Applied could not overcome Medtronic's overall bundle.
- d. The \$1.6 million cost savings proposal for switching to Voyant could not touch the rebate check provided by Medtronic based on broad categories of devices.
- e. The hospital recognized the significant value that Applied provided. But could not purchase from Applied because of a bundled contract with Medtronic.
- f. The hospital acknowledged that Applied had offered huge savings for switching to Voyant. But that was not enough to overcome Medtronic's bundle.
- g. Applied had the most line-item savings. But Applied could not overcome Medtronic's bundle of vessel sealing and stapling products.
- h. The hospital's agreement with Medtronic prevented the hospital from exploring the benefits of switching to Voyant.
- i. Despite strong surgeon support, the hospital could not move forward with Applied due to the hospital's bundled contract with Medtronic.
- j. Despite savings of about \$1.5 million, the hospital's bundled agreement with Medtronic prevented it from purchasing Voyant.

k. Despite strong surgeon support, at least one official request for Voyant was denied because switching to Voyant would erode the health system's financial obligations to Medtronic.

G. Applied's Antitrust Injury and Standing

1. Applied's Antitrust Injury

- 122. Applied has suffered losses as a direct consequence of the anticompetitive aspects of Medtronic's conduct. Medtronic has substantially foreclosed competition through its anticompetitive conduct discussed above. Medtronic holds a monopoly position in the advanced bipolar device market and employs anticompetitive business practices that serve only or principally to impede Applied and other rivals from offering competitive products. Applied's injuries are of the type the antitrust laws were intended to prevent and flow from that which makes Medtronic's acts unlawful because Applied is a direct competitor in the relevant market for advanced bipolar devices. Medtronic has prevented Applied from making significant headway in the relevant market and deprived consumers of access to Applied's better-performing and lower-cost Voyant products.
- 123. Among other things, Medtronic's anticompetitive behavior has caused Applied to lose profits from the sale of Voyant to hospitals. Medtronic's anticompetitive conduct forecloses a substantial portion of the market and prevents many consumers from even considering Applied's products.
- 124. As discussed above, many hospitals have informed Applied that they could not purchase Voyant because of contracts with Medtronic. For example: New York University, Mt. Sinai, Westchester New York, Lehigh Valley, Sentara, Tift, Memorial Hermann, Ochsner Health, Community Memorial Health System, Captis Healthcare Organization, Emory, UPMC, Cleveland Clinic, Robert Wood Johnson, Main Line Health, Tampa General, Parkview, Northwestern, Mercy St.

Louis, Banner, University of Utah, and University of California health systems (including UCLA).

125. Applied has lost profits from the ongoing sales it would have made of consumables used as part of Voyant. Further, Medtronic's anticompetitive suppression of Applied's technology has also harmed Applied's brand and goodwill. Medtronic's largely successful efforts to prevent Applied from entering the advanced bipolar market prevents Applied from showcasing its superior products to potential customers. In particular, Applied cannot demonstrate to many surgeons that its devices perform better and are far less expensive than the Medtronic's products. This harms Applied's ability to expand and compete for sales of other medical devices.

126. Medtronic's anticompetitive abuses have thus caused Applied to suffer large, ongoing losses of profits and opportunities as well as significant erosion of its goodwill and brand. All of Applied's above-described losses are antitrust injuries -i.e., losses proximately caused by the anticompetitive aspects and character of Medtronic's conduct. The full extent of Applied's losses will be demonstrated at a later stage of these proceedings.

2. Applied's Antitrust Standing

127. Applied has antitrust standing to bring the present claims for many reasons. As alleged above, Applied has suffered antitrust injury. Applied is a seller of advanced bipolar devices and has lost profits on sales of such devices in the advanced bipolar device market. These lost sales also cause Applied to lose sales and profits on the system accessories that hospitals periodically purchase for use in these systems. Moreover, Applied engages in ongoing, extensive efforts to convince hospitals to purchase advanced bipolar devices. Owing to Medtronic's above anticompetitive practices, Applied has suffered direct, large, and ongoing losses.

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- 128. The other relevant factors also show that Applied has antitrust standing and should be permitted to bring this suit. There is a direct causal connection between Medtronic's antitrust violations, the harm Applied is suffering, and Medtronic's intent to cause harm to Applied.
- 129. Medtronic has identified Applied as a disruptive competitor whose superior, lower-priced Voyant products pose a disruptive threat to Medtronic's monopoly in the market for advanced bipolar devices. As discussed, Medtronic has targeted some anticompetitive conduct specifically at Applied. Additionally, prior to the merger between Medtronic and Covidien, Covidien had a "Playbook" specifically targeting Applied and explaining how to engage in anticompetitive acts to prevent Applied from succeeding in selling trocars. The Covidien Playbook discussed how to create bundles and "leverage" Covidien's much larger portfolio of products to prevent Applied from making headway in the trocar market. That playbook did not provide any selling points on differentiating quality, performance, or price. Instead, it focused on leveraging the bundle. On information and belief, based on Applied's recent experiences with hospitals, Medtronic's sales staff is currently using the same or similar approach. These targeting efforts support a direct causal connection between Medtronic's antitrust violations, the harm Applied is suffering, and Medtronic's intent to cause that harm.
- 130. As discussed above, Applied's injuries are of the type the antitrust laws were intended to address. In particular, Applied has been unable to make significant headway in the advanced bipolar market even though it makes better products at lower prices. Denying consumers access to better products at lower prices is precisely the type of harm that the antitrust laws were intended to address.
- 131. Applied's motives in this case also coincide with the public policies of antitrust law. Applied seeks an injunction that will prevent Medtronic from

engaging in anticompetitive acts in the future that are harming competition, Applied, and other competitors in the advanced bipolar market. Enjoining Medtronic's anticompetitive behavior will open the market for advanced bipolar devices, allowing Applied and other competitors to compete fairly. As a result, the goals of the antitrust laws will be achieved by encouraging free and open competition, which will increase product quality and innovation while driving prices down. A successful lawsuit will also deter Medtronic and others from engaging in similar anticompetitive acts in other markets, which furthers the goals of the antitrust laws by opening up other markets to more competition.

- 132. Applied is also the most direct victim of Medtronic's conduct. Applied is one of the most, if not the most, efficient competitors in the market. Applied prides itself on vertical integration that allows it to produce premium products at a lower cost than its competitors. Applied is uniquely positioned to drive prices down across the advanced bipolar market—just like it did for trocars.
- 133. Applied is also uniquely situated to complain of the above-pleaded antitrust wrongs and to demonstrate their occurrence and anticompetitive effects. Applied has unique insight into these practices and evidence to prove their occurrence and their injurious effects on competitive processes in the affected markets. Perhaps more than any other market participant, Applied has the evidence, understanding, direct knowledge, financial interest, and resources to state, develop, and present these antitrust claims.
- 134. Finally, there is no significant risk of duplicative recovery or complex apportionment. Applied's losses directly flow from the anticompetitive conduct it now challenges. There is no risk of an improper allocation of these losses among various claimants, nor any risk that Medtronic will be ordered to pay the same damages twice if it is ordered to compensate Applied for Applied's antitrust injuries. This case does not involve other parties or "downstream" actors that would be competing for the same pool of profits garnered by Medtronic's

anticompetitive acts. Applied's losses are not speculative, remote, or tenuously connected to Medtronic's antitrust misconduct. In addition, Medtronic's anticompetitive misconduct has directly and significantly harmed Applied in the manner pleaded above and in the very market in which Medtronic has committed its anticompetitive acts. Applied therefore has antitrust standing to assert its present antitrust challenge against Medtronic.

V. FIRST CAUSE OF ACTION: MONOPOLIZATION (15 U.S.C. § 2)

- 135. Applied realleges and incorporates by reference the allegations stated in paragraphs 1-134 of this Complaint as if fully set forth herein.
- 136. For purposes of antitrust review, there exists a relevant market, or in the alternative submarket, for the sale of advanced bipolar devices in the United States.
- 137. Medtronic has monopoly power in the advanced bipolar device market. Medtronic has a market share of about 78%. Its position in this market is protected by high barriers to entry and expansion. Medtronic also imposes supracompetitive prices in the relevant market.
- 138. Medtronic has willfully acquired and maintained monopoly power in this market through the above-pleaded exclusionary and anticompetitive means. Medtronic is engaged in an ongoing and overarching anticompetitive scheme designed to maintain its monopoly power in the market for advanced bipolar devices. By engaging in the above-pleaded conduct, Medtronic is abusing and has abused its monopoly power, and severely impeded and undermined competition in the market for advanced bipolar devices, thereby entrenching and enlarging its monopoly position.
- 139. Medtronic is not competing on the merits and does not have a more efficient production or superior product quality. Instead, Medtronic obtained and maintained its dominant share of the market through a variety of anticompetitive means. Medtronic's conduct has directly resulted in demonstrable harm to

competitive processes in the affected markets, including an adverse effect on prices, fewer choices and inferior products, and limiting rivals' market penetration. Medtronic's unlawful conduct has and will directly and proximately cause injury or loss to interstate commerce and to hospitals.

- 140. Medtronic's unlawful conduct further harms competition and thereby causes and threatens injury or loss to Applied's business, property, and competitive position, which will continue unless Medtronic's anticompetitive conduct is enjoined. Specifically, Applied has lost and will lose millions of dollars in sales and profits from within the market for advanced bipolar devices that would take place but for Medtronic's behavior. Applied's injuries are of the type that antitrust laws are intended to prohibit, and flow directly from Medtronic's anticompetitive conduct in violation of Section 2 of the Sherman Act.
- 141. Without injunctive relief, Medtronic will continue to monopolize and restrain trade in the market for advanced bipolar devices, harming hospitals and excluding rivals to keep its monopoly position.
- 142. Medtronic's conduct thus violates Section 2 of the Sherman Act, 15 U.S.C. § 2.

VI. <u>SECOND CAUSE OF ACTION: ATTEMPTED</u> <u>MONOPOLIZATION (15 U.S.C. § 2)</u>

- 143. Applied realleges and incorporates by reference the allegations stated in paragraphs 1-142 of this Complaint as if fully set forth herein.
- 144. For purposes of antitrust review, there exists a relevant market, or in the alternative submarket, for the sale of advanced bipolar devices in the United States.
- 145. To the extent Medtronic does not already have monopoly power in the advanced bipolar devices market, and in the alternative, there is a dangerous probability Medtronic will acquire that power through its anticompetitive

conduct. Medtronic is willfully engaging in the above-pleaded course of conduct, including anticompetitive and exclusionary actions, with the specific intent of achieving monopoly power and monopolizing this market. Medtronic is engaged in an ongoing and overarching anticompetitive scheme designed to obtain monopoly power in the advanced bipolar devices market. By engaging in the above-pleaded conduct, Medtronic is abusing and has abused its monopoly power, and severely impeded and undermined competition in the market for advanced bipolar devices, thereby entrenching and enlarging its monopoly position. There is at least a dangerous probability that, unless restrained, Medtronic will succeed in obtaining monopoly power in the advanced bipolar devices market.

146. Medtronic is not competing on the merits and does not have a more

- 146. Medtronic is not competing on the merits and does not have a more efficient production or superior product quality. Instead, Medtronic is obtaining or, in the alternative, is attempting to obtain, its dominant share of the market through a variety of anticompetitive means. Medtronic's conduct has directly resulted in demonstrable harm to competitive processes in the affected markets, including an adverse effect on prices, fewer choices and inferior products, and limiting rivals' market penetration. Medtronic's unlawful conduct will directly and proximately cause injury or loss to interstate commerce and to hospitals.
- 147. Medtronic's unlawful conduct further harms competition and thereby causes and threatens injury or loss to Applied's business, property, and competitive position, which will continue unless Medtronic's anticompetitive conduct is restrained by the issuance of injunctive relief. Specifically, Applied has lost and will lose substantial sales and profits from within the advanced bipolar devices market that would take place but for Medtronic's behavior. Applied's injuries are of the type that antitrust laws are intended to prohibit, and flow directly from Medtronic's anticompetitive conduct in violation of Section 2 of the Sherman Act.

- 148. Without injunctive relief, Medtronic will continue to attempt to monopolize and restrain trade in the market for advanced bipolar devices, harming hospitals and excluding rivals to keep its monopoly position.
- 149. Medtronic's conduct thus violates Section 2 of the Sherman Act, 15 U.S.C. § 2.

VII. THIRD CAUSE OF ACTION: UNLAWFUL RESTRAINT OF TRADE (15 U.S.C. § 1)

- 150. Applied realleges and incorporates by reference the allegations stated in paragraphs 1-149 of this Complaint as if fully set forth herein.
- 151. For purposes of antitrust review, there exists a relevant market, or in the alternative submarket, for the sale of advanced bipolar devices in the United States.
- 152. Medtronic has substantial market power in the advanced bipolar device market. Medtronic has a market share of about 78% in that market. Its position in this market is protected by high barriers to entry and expansion. Medtronic imposes supracompetitive prices in the relevant market.
- 153. As discussed above, Medtronic has engaged in exclusive dealing and entered into anticompetitive agreements with GPOs and hospitals. Such agreements include "sole-source" agreements with GPOs, requirements contracts with hospitals, and exclusionary bundling agreements. Such agreements in practice require hospitals to purchase all or nearly all their advanced bipolar devices from Medtronic for long periods of time.
- 154. Through its agreements and arrangements, Medtronic has succeeded in restraining trade, causing demonstrable harm to competition in the relevant market, as fully pleaded above. Medtronic has substantially foreclosed competition in greater than 70% of the above-pleaded market.
- 155. On balance, Medtronic's above-pleaded practices have cumulatively undermined competitive processes in the relevant market more than they have

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27 28 furthered any legitimate, pro-competitive purpose. If Medtronic had any legitimate, pro-competitive purpose for any of the above practices, it could have accomplished each such purpose by less restrictive methods that did not have the same anticompetitive effects.

- 156. Medtronic's conduct has directly resulted in demonstrable harm to competitive processes in the affected markets, including an adverse effect on prices, fewer choices and inferior products, and limiting rivals' market penetration. Medtronic's unlawful conduct has and will directly and proximately cause injury or loss to competition and customers in the relevant market.
- 157. Medtronic's unlawful conduct further harms competition and thereby causes and threatens injury or loss to Applied's business, property, and competitive position, which will continue unless Medtronic's anticompetitive conduct is enjoined. Specifically, Applied has lost and will lose millions of dollars in sales and profits from within the market for advanced bipolar devices that would take place but for Medtronic's behavior. Applied's injuries are of the type that antitrust laws are intended to prohibit, and flow directly from Medtronic's anticompetitive conduct in violation of Section 1 of the Sherman Act.
- 158. Without injunctive relief, Medtronic will continue to restrain trade in the market for advanced bipolar devices, harming hospitals and excluding rivals to keep its monopoly position.
- 159. By so acting, Medtronic has employed trade practices that constitute unlawful restraints of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

VIII. FOURTH CAUSE OF ACTION: ANTICOMPETITIVE **BUNDLING (15 U.S.C. § 1)**

160. Applied realleges and incorporates by reference the allegations stated in paragraphs 1-159 of this Complaint as if fully set forth herein.

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- 161. For purposes of antitrust review, there exists a relevant market, or in the alternative submarket, for the sale of advanced bipolar devices in the United States.
- 162. Medtronic has substantial market power in the advanced bipolar device market. Medtronic has a market share of about 78% in that market. Its position in this market is protected by high barriers to entry and expansion. Medtronic imposes supracompetitive prices in the relevant market.
- 163. As discussed above, Medtronic has engaged in anticompetitive exclusionary bundling whereby Medtronic conditions discounts and rebates on the purchase of a variety of devices, including advanced bipolar devices, monopolar devices, stapling, and other products. The quantities and revenue of advanced bipolar devices ordered as part of these bundles is much smaller than the quantities and revenue of the other devices. Competitors cannot profitably offer advanced bipolar devices when competing with the bundle because the exclusionary discount on the bundle far exceeds any reduction in price that could be available from an equally efficient competitor. Medtronic is selling its advanced bipolar devices below its average variable costs, after allocating the exclusionary discount given by Medtronic on the entire bundle to the advanced bipolar devices.
- 164. Medtronic's bundling unlawfully restrains trade by excluding equally and more efficient competitors from the advanced bipolar device market. Medtronic's bundling substantially forecloses competition both with respect to cost and the choice of, and access to, better surgical devices. This is to the detriment of health insurers, and ultimately consumers, in the form of higher prices paid for lower quality surgical devices, which contributes to high insurance costs that result in some patients being uninsured and unable to afford life-saving procedures.

- 165. On balance, Medtronic's above-pleaded practices have cumulatively undermined competitive processes in the relevant market more than they have furthered any legitimate, pro-competitive purpose. If Medtronic had any legitimate, pro-competitive purpose for any of the above practices, it could have accomplished each such purpose by less restrictive methods that did not have the same anticompetitive effects.
- 166. Medtronic's conduct has directly resulted in demonstrable harm to competitive processes in the affected markets, including an adverse effect on prices, fewer choices and inferior products, and limiting rivals' market penetration. Medtronic's unlawful conduct has and will directly and proximately cause injury or loss to competition and customers in the relevant market.
- 167. Medtronic's unlawful conduct further harms competition and thereby causes and threatens injury or loss to Applied's business, property, and competitive position, which will continue unless Medtronic's anticompetitive conduct is enjoined. Specifically, Applied has lost and will lose millions of dollars in sales and profits from within the market for advanced bipolar devices that would take place but for Medtronic's behavior. Applied's injuries are of the type that antitrust laws are intended to prohibit, and flow directly from Medtronic's anticompetitive bundling in violation of Section 1 of the Sherman Act.
- 168. Without injunctive relief, Medtronic will continue to restrain trade in the market for advanced bipolar devices, harming hospitals and excluding rivals to keep its monopoly position.
- 169. By so acting, Medtronic has employed trade practices that constitute unlawful restraints of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

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IX. FIFTH CAUSE OF ACTION: EXCLUSIVE DEALING (15 U.S.C. §§ 1, 14)

- Applied realleges and incorporates by reference the allegations stated in paragraphs 1-169 of this Complaint as if fully set forth herein.
- 171. For purposes of antitrust review, there exists a relevant market, or in the alternative submarket, for the sale of advanced bipolar devices in the United States.
- 172. Medtronic has substantial market power in the advanced bipolar device market. Medtronic has a market share of about 78% in that market. Its position in this market is protected by high barriers to entry and expansion. Medtronic imposes supracompetitive prices in the relevant market.
- 173. As discussed above, Medtronic has engaged in exclusive dealing and entered into anticompetitive agreements with GPOs and hospitals. Such agreements include "sole-source" agreements with GPOs, requirements contracts with hospitals, and exclusionary bundling agreements. Such agreements in practice require hospitals to purchase all or nearly all their advanced bipolar devices from Medtronic for long periods of time.
- 174. Through its agreements and arrangements, Medtronic has succeeded in restraining trade, causing demonstrable harm to competition in the relevant market, as is fully pleaded above. Medtronic has substantially foreclosed competition in greater than 70% of the above-pleaded market.
- 175. By using these trade restraints, Medtronic has intended to restrain commerce for its own benefit. Medtronic has succeeded in restraining trade and lessening competition, causing demonstrable harm to competition in the relevant market, as is fully pleaded above.
- 176. On balance, Medtronic's above-pleaded practices have cumulatively undermined competitive processes in the relevant market more than they have If Medtronic had any furthered any legitimate, pro-competitive purpose.

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legitimate, pro-competitive purpose for any of the above practices, it could have accomplished each such purpose by less restrictive methods that did not have the same anticompetitive effects.

177. Medtronic's conduct has directly resulted in demonstrable harm to competitive processes in the affected markets, including an adverse effect on prices, fewer choices and inferior products, and limiting rivals' market penetration. Medtronic's unlawful conduct has and will directly and proximately cause injury or loss to competition and customers in the relevant market.

178. Medtronic's unlawful conduct further harms competition and thereby causes and threatens injury or loss to Applied's business, property, and competitive position, which will continue unless Medtronic's anticompetitive conduct is enjoined. Specifically, Applied has lost and will lose millions of dollars in sales and profits from within the market for advanced bipolar devices that would take place but for Medtronic's behavior. Applied's injuries are of the type that antitrust laws are intended to prohibit, and flow directly from Medtronic's anticompetitive conduct in violation of Section 3 of the Clayton Act.

- 179. Without injunctive relief, Medtronic will continue to restrain trade in the market for advanced bipolar devices, harming hospitals and excluding rivals to keep its monopoly position.
- 180. By so acting, Medtronic has employed trade practices that constitute exclusive dealing in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1 and Section 3 of the Clayton Act, 15 U.S.C. § 14.

X. <u>SIXTH CAUSE OF ACTION: UNLAWFUL RESTRAINT OF TRADE</u> (CALIFORNIA CARTWRIGHT ACT)

181. Applied realleges and incorporates by reference the allegations stated in paragraphs 1-180 of this Complaint as if fully set forth herein.

- 182. For purposes of antitrust review, there exists a relevant market, or in the alternative submarket, for the sale of advanced bipolar devices in the United States.
- 183. Medtronic has market power in the advanced bipolar device market. Medtronic has a market share of about 78% in that market. Its position in this market is protected by high barriers to entry and expansion. Medtronic imposes supracompetitive prices in the relevant market.
- 184. As discussed above, Medtronic has engaged in exclusive dealing and entered into anticompetitive agreements with GPOs and hospitals. Such agreements include "sole-source" agreements with GPOs, requirements contracts with hospitals, and exclusionary bundling agreements. Such agreements in practice require hospitals to purchase all or nearly all their advanced bipolar devices from Medtronic for long periods of time.
- 185. Through its agreements and arrangements, Medtronic has succeeded in restraining trade, causing demonstrable harm to competition in the relevant market, as is fully pleaded above. Medtronic has substantially foreclosed competition in greater than 70% of the above-pleaded market.
- 186. On balance, Medtronic's above-pleaded practices have cumulatively undermined competitive processes in the relevant market more than they have furthered any legitimate, pro-competitive purpose. If Medtronic had any legitimate, pro-competitive purpose for any of the above practices, they could have accomplished each such purpose by less restrictive methods that did not have the same anticompetitive effects.
- 187. Medtronic's conduct has directly resulted in demonstrable harm to competitive processes in the affected markets, including an adverse effect on prices, fewer choices and inferior products, and limiting rivals' market penetration. Medtronic's unlawful conduct has and will directly and proximately cause injury or loss to competition and customers in the relevant market.

188. Medtronic's unlawful conduct further harms competition and thereby causes and threatens injury or loss to Applied's business, property, and competitive position, which will continue unless Medtronic's anticompetitive conduct is enjoined. Specifically, Applied has lost and will lose millions of dollars in sales and profits from within the market for advanced bipolar devices that would take place but for Medtronic's behavior. Applied's injuries are of the type that antitrust laws are intended to prohibit, and flow directly from Medtronic's anticompetitive conduct in violation of the Cartwright Act, Cal. Bus. & Prof. Code §§ 16700, et seq.

- 189. Without injunctive relief, Medtronic will continue to restrain trade in the market for advanced bipolar devices, harming hospitals and excluding rivals to keep its monopoly position.
- 190. By so acting, Medtronic has employed trade practices that constitute unlawful restraints of trade in violation of Cartwright Act, Cal. Bus. & Prof. Code §§ 16700, et seq.

XI. SEVENTH CAUSE OF ACTION: UNLAWFUL INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE

- 191. Applied realleges and incorporates by reference the allegations stated in paragraphs 1-190 of this Complaint as if fully set forth herein.
- 192. Applied had a reasonable expectation of economic advantage and benefit from marketing and selling Voyant in the advanced bipolar devices market and from entering into agreements with hospitals. In addition, Applied had a reasonable expectation of economic advantage and benefit from capturing a material share of the advanced bipolar devices market, since Voyant has the same functions and features as Medtronic's Ligasure, performs better, and costs significantly less.
- 193. Among others, Medtronic has interfered with at least the following prospective customers of Applied: New York University, Mt. Sinai, Westchester

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New York, Lehigh Valley, Sentara, Tift, Memorial Hermann, Ochsner Health, Community Memorial Health System, Captis Healthcare Organization, Emory, UPMC, Cleveland Clinic, Robert Wood Johnson, Main Line Health, Tampa General, Parkview, Northwestern, Mercy St. Louis, Banner, University of Utah, and University of California health systems (including UCLA).

- 194. Medtronic knew that Applied had a reasonable expectation of economic advantage and benefit through business relations with hospitals. Without justification, Medtronic intentionally and wrongfully interfered with Applied's expected economic advantage and benefit by, among other things, engaging in the anticompetitive conduct discussed above, targeting specific hospitals with which Applied was making inroads, coercing hospitals to cease negotiations with Applied, and deceptively promising illusory discounts to induce hospitals to exclude Voyant. Medtronic intentionally took such measures to restrain hospitals from purchasing Voyant, thus, effectively excluding Applied from the advanced bipolar devices market.
- 195. As a direct result of Medtronic's intentional and wrongful interference, hospitals have been dissuaded from purchasing Voyant, thereby destroying Applied's expected economic advantage and benefit.
- 196. But for Medtronic's interference, there was a reasonable probability that Applied would receive the economic advantage and benefits resulting from its sale of Voyant in the advanced bipolar devices market and would thereafter capture a material share of the advanced bipolar devices market.
- 197. Medtronic had no adequate justification to interfere with Applied's economic advantage and benefit. Medtronic's conduct is outrageous and against the public interest because Medtronic acted with malice and/or reckless indifference to the rights of others.

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- 198. Medtronic's interference with Applied's economic advantage and benefit has caused and will continue to cause Applied to suffer damages, including lost profits and other damages.
- 199. Upon information and belief, Medtronic's acts of unlawful interference will continue unless restrained by this Court.
- 200. Applied is entitled to injunctive relief and such other relief as this cause of action allows.

XII. EIGHTH CAUSE OF ACTION: UNFAIR COMPETITION (CAL. BUS. & PROF CODE § 17200)

- 201. Applied realleges and incorporates by reference the allegations stated in paragraphs 1-200 of this Complaint as if fully set forth herein.
- 202. Medtronic's conduct, as described above, violates California's Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200, et seq., which prohibits any unlawful, unfair, or fraudulent business act or practice.
- 203. Applied has standing to bring this claim because it has suffered injury in fact and lost money as a result of Medtronic's unfair competition. On information and belief, Medtronic engaged in the activities alleged herein for the purpose and with the intent of injuring Applied's business and property in California.
- 204. Medtronic's conduct violates the Sherman Act, Clayton Act, and the Cartwright Act, and thus constitutes "unlawful" conduct under § 17200.
- 205. Medtronic's conduct is also "unfair" within the meaning of the Unfair Competition law. Medtronic's conduct constitutes at least an incipient violation of the antitrust laws, and a violation of the policy and spirit of those laws with comparable effects.
- 206. By reason of and as a direct and proximate result of Medtronic's unfair acts, practices, and policies, Applied has been injured in its business and property in California.

PRAYER FOR RELIEF WHEREFORE, Applied requests relief from this Court as follows: 2 3 A jury trial on all issues so triable; A. A declaration that Medtronic has violated Sections 1 and 2 of the В. 4 5 Sherman Act (15 U.S.C. §§ 1-2), Section 3 of the Clayton Act (15 U.S.C. § 14), the California Cartwright Act (Cal. Bus. & Prof. Code § 16700), and California 6 Unfair Competition (Cal. Bus. & Prof. Code § 17200); 7 A declaration that Medtronic has committed unlawful interference 8 C. with prospective economic advantage; 9 10 D. Monetary damages to compensate Applied for its injuries, a trebling of these damages, costs, and attorney's fees, as authorized under 15 U.S.C. § 15 11 and Cal. Bus. & Prof. Code §§ 16750; 12 13 Ε. Injunctive relief from each of Medtronic's anticompetitive and unlawful commercial practices, as authorized under 15 U.S.C. § 26, Cal. Bus. & 14 Prof. Code §§ 16750, and Cal. Bus. & Prof. Code §§ 17200; 15 Monetary damages and injunctive relief under applicable California 16 F. 17 common law; 18 G. Prejudgment interest; and An Order awarding any further relief deemed equitable and just by 19 Η. this Court. 20 21 Respectfully submitted, KNOBBE, MARTENS, OLSON & BEAR, LLP 22 23 24 Dated: February 13, 2023 By: /s/ Stephen W. Larson Stephen C. Jensen 25 Stephen W. Larson Adam B. Powell 26 Attorneys for Plaintiff 27 APPLIED MEDICAL RESOURCES CORPORATION 28

DEMAND FOR JURY TRIAL Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff Applied Medical Resources Corporation demands a trial by jury of all issues raised by the pleadings which are triable by jury. Respectfully submitted, KNOBBE, MARTENS, OLSON & BEAR, LLP Dated: February 13, 2023 By: /s/ Stephen W. Larson Stephen C. Jensen Stephen W. Larson Adam B. Powell Attorneys for Plaintiff APPLIÉD MEDICAL RESOURCES CORPORATION